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09/806,801	04/04/2001	Staffan Folestad	1103326-0659	6014

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EXAMINER	
JACKSON, ANDRE K	
ART UNIT	PAPER NUMBER
2856	

DATE MAILED: 05/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/806,801	FOLESTAD ET AL.	
	Examiner	Art Unit	
	André K. Jackson	2856	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,6-23,25 and 26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6-23,25 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-3,6-13,17 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hammond et al. in view of Trygstad and Soloman.

Regarding claim 1, Hammond et al. disclose "Spectrophotometric analysis" which has a means for feeding one sample through at least one predetermined analyzing position (Column 4, lines 1-11) and a means for temporarily fixing the sample in the analyzing position, where the fixing means comprises a first (8) and a second (12) holding part arranged at the analyzing position and where the holding parts are adapted to move between an open position when the sample is provided for analysis and a closed position when the sample is analyzed. What is not disclosed by Hammond et al. is where the first and second holding parts defines apertures within the parts and where the first and second apertures together define an effective aperture in the closed position. However, Trygstad discloses in "Measurement of transmission spectra of pharmaceutical tablets" where the first and second holding parts defines

apertures within the parts and where the first and second apertures together define an effective aperture in the closed position (Figures 1 and 2; 30,36). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Hammond et al. to include where the first and second holding parts defines apertures within the parts and where the first and second apertures together define an effective aperture in the closed position as taught by Trygstad. By adding this feature the artisan would be able to analyze tablets of various sizes. Neither Hammond et al. nor Trygstad disclose an automated means for feeding one or more samples sequentially through a predetermined analyzing position. Soloman discloses in the patent entitled "Non destructive identification of tablet and tablet dissolution by means of infrared spectroscopy" an automated means for feeding one or more samples sequentially through a predetermined analyzing position (Abstract, Column1). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Hammond to include an automated means for feeding one or more samples sequentially through a predetermined analyzing position. By adding this feature the apparatus would be able to precisely feed the samples during the analyzing process.

Regarding claim 2, Hammond et al. do not disclose where the first and second holding parts are located on opposite sides of the sample when in the closed position. However, Trygstad discloses where the first and second holding parts are located on opposite sides of the sample when in the closed position

(Figure 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Hammond et al. to include where the first and second holding parts are located on opposite sides of the sample when in the closed position as taught by Trygstad. By adding this arrangement the sample would remain in a stable position.

Regarding claim 3, Hammond et al. disclose where the first and second holding parts do not contact the sample in the open position (Column 12, lines 22-52).

Regarding claim 6, Hammond et al. disclose where the first and second holding parts each define a first and second compartment, which together define a predetermined volume (Figure 2).

Regarding claim 7, Hammond et al. disclose where the means for feeding samples through the analyzing position comprises one pre-alignment means for receiving and holding a sample during transport of the sample to the analyzing position (Figure 2).

Regarding claims 8 and 9, Hammond et al. do not disclose where the pre-alignment means comprises an elastically compressible member for flexibly engaging the sample. It is considered a design choice to have an elastically compressible member for flexibly engaging the sample to keep the sample from chipping or breaking.

Regarding claim 10, Hammond et al. disclose where the pre-alignment means comprise a spring-loaded arm for embracing the sample (Figure 2).

Regarding claim 11, Hammond et al. disclose where spring-loaded arm and a part of the feeding means are provided with an indentation for receiving the sample (Figure 1).

Regarding claim 12, neither Hammond et al. nor Trygstad disclose where the means for feeding samples sequentially through the analyzing position is a rotating feeder wheel comprising at least one pre-alignment means for receiving at least one sample. However, Soloman discloses a means for feeding samples sequentially through the analyzing position is a rotating feeder wheel comprising at least one pre-alignment means for receiving at least one sample (Figure 1-2). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Hammond et al. to include a means for feeding samples sequentially through the analyzing position is a rotating feeder wheel comprising at least one pre-alignment means for receiving at least one sample since it would make it easier to analyze more samples in a shorter period of time.

Regarding claim 13, neither Hammond et al. nor Trygstad disclose where the rotating feeder wheel is connected to a sample receiver, which provides the feeder with samples to be analyzed. However, Soloman discloses where the rotating feeder wheel is connected to a sample receiver, which provides the feeder with samples to be analyzed (Figures 1-2). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Hammond et al. to include where the rotating feeder wheel is connected to a

sample receiver which provides the feeder with samples to be analyzed since it would provide an even distribution of tablets.

Regarding claim 17, Hammond et al. disclose where the sample is a solid dosage form (Figure 2).

Regarding claim 26, Hammond et al. disclose where the dosage is a tablet (Figure 2).

3. Claims 1-3,6-14,17 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hammond et al. in view of Trygstad and Kajiura et al.

Regarding claim 1, Hammond et al. disclose a means for feeding one sample through at least one predetermined analyzing position (Column 4, lines 1-11) and a means for temporarily fixing the sample in the analyzing position, where the fixing means comprises a first (8) and a second (12) holding part arranged at the analyzing position and where the holding parts are adapted to move between an open position when the sample is provided for analysis and a closed position when the sample is analyzed. What is not disclosed by Hammond et al. is where the first and second holding parts defines apertures within the parts and where the first and second apertures together define an effective aperture in the closed position. However, Trygstad discloses where the first and second holding parts define apertures within the parts and where the first and second apertures together define an effective aperture in the closed position (Figures 1 and 2; 30,36). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Hammond

et al. to include where the first and second holding parts defines apertures within the parts and where the first and second apertures together define an effective aperture in the closed position as taught by Trygstad. By adding this feature the artisan would be able to analyze tablets of various sizes. Neither Hammond et al. nor Trygstad disclose an automated means for feeding one or more samples sequentially through a predetermined analyzing position. Kajiura et al. disclose in the patent entitled "External appearance inspecting system" an automated means for feeding one or more samples sequentially through a predetermined analyzing position (Figure 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Hammond to include an automated means for feeding one or more samples sequentially through a predetermined analyzing position. By adding this feature the apparatus would be able to precisely feed the samples during the analyzing process.

Regarding claim 2, Hammond et al. do not disclose where the first and second holding parts are located on opposite sides of the sample when in the closed position. However, Trygstad discloses where the first and second holding parts are located on opposite sides of the sample when in the closed position (Figure 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Hammond et al. to include where the first and second holding parts are located on opposite sides of the

sample when in the closed position as taught by Trygstad. By adding this arrangement the sample would remain in a stable position.

Regarding claim 3, Hammond et al. disclose where the first and second holding parts do not contact the sample in the open position (Column 12, lines 22-52).

Regarding claim 6, Hammond et al. disclose where the first and second holding parts each define a first and second compartment, which together define a predetermined volume (Figure 2).

Regarding claim 7, Hammond et al. disclose where the means for feeding samples through the analyzing position comprises one pre-alignment means for receiving and holding a sample during transport of the sample to the analyzing position (Figure 2).

Regarding claims 8 and 9, Hammond et al. do not disclose where the pre-alignment means comprises an elastically compressible member for flexibly engaging the sample. It is considered a design choice to have an elastically compressible member for flexibly engaging the sample to keep the sample from chipping or breaking.

Regarding claim 10, Hammond et al. disclose where the pre-alignment means comprise a spring-loaded arm for embracing the sample (Figure 2).

Regarding claim 11, Hammond et al. disclose where spring-loaded arm and a part of the feeding means are provided with an indentation for receiving the sample (Figure 1).

Regarding claim 12, neither Hammond et al. nor Trygstad disclose where the means for feeding samples sequentially through the analyzing position is a rotating feeder wheel comprising at least one pre-alignment means for receiving at least one sample. However, Kajiura et al. disclose a means for feeding samples sequentially through the analyzing position is a rotating feeder wheel comprising at least one pre-alignment means for receiving at least one sample (Figure 1-2). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Hammond et al. to include a means for feeding samples sequentially through the analyzing position is a rotating feeder wheel comprising at least one pre-alignment means for receiving at least one sample since it would make it easier to analyze more samples in a shorter period of time.

Regarding claim 13, neither Hammond et al. nor Trygstad disclose where the rotating feeder wheel is connected to a sample receiver, which provides the feeder with samples to be analyzed. However, Kajiura et al. disclose where the rotating feeder wheel is connected to a sample receiver, which provides the feeder with samples to be analyzed (Figures 1-2). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Hammond et al. to include where the rotating feeder wheel is connected to a sample receiver which provides the feeder with samples to be analyzed since it would provide an even distribution of tablets.

Regarding claim 17, Hammond et al. disclose where the sample is a solid dosage form (Figure 2).

Regarding claim 26, Hammond et al. disclose where the dosage is a tablet (Figure 2).

4. Claims 1-3,6-17,25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hammond et al. in view of Trygstad and Schilling.

Regarding claim 1, Hammond et al. disclose a means for feeding one sample through at least one predetermined analyzing position (Column 4, lines 1-11) and a means for temporarily fixing the sample in the analyzing position, where the fixing means comprises a first (8) and a second (12) holding part arranged at the analyzing position and where the holding parts are adapted to move between an open position when the sample is provided for analysis and a closed position when the sample is analyzed. What is not disclosed by Hammond et al. is where the first and second holding parts defines apertures within the parts and where the first and second apertures together define an effective aperture in the closed position. However, Trygstad discloses where the first and second holding parts define apertures within the parts and where the first and second apertures together define an effective aperture in the closed position (Figures 1 and 2; 30,36). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Hammond et al. to include where the first and second holding parts defines apertures within the parts and where the first and second apertures together define an effective

aperture in the closed position as taught by Trygstad. By adding this feature the artisan would be able to analyze tablets of various sizes. Neither Hammond et al. nor Trygstad disclose an automated means for feeding one or more samples sequentially through a predetermined analyzing position. Schilling discloses in the patent entitled "Sorting arrangement" an automated means for feeding one or more samples sequentially through a predetermined analyzing position, as disclosed by the Applicant on page 2, line 29 of the instant application. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Hammond to include an automated means for feeding one or more samples sequentially through a predetermined analyzing position. By adding this feature the apparatus would be able to precisely feed the samples during the analyzing process.

Regarding claim 2, Hammond et al. do not disclose where the first and second holding parts are located on opposite sides of the sample when in the closed position. However, Trygstad discloses where the first and second holding parts are located on opposite sides of the sample when in the closed position (Figure 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Hammond et al. to include where the first and second holding parts are located on opposite sides of the sample when in the closed position as taught by Trygstad. By adding this arrangement the sample would remain in a stable position.

Regarding claim 3, Hammond et al. disclose where the first and second holding parts do not contact the sample in the open position (Column 12, lines 22-52).

Regarding claim 6, Hammond et al. disclose where the first and second holding parts each define a first and second compartment, which together define a predetermined volume (Figure 2).

Regarding claim 7, Hammond et al. disclose where the means for feeding samples through the analyzing position comprises one pre-alignment means for receiving and holding a sample during transport of the sample to the analyzing position (Figure 2).

Regarding claims 8 and 9, Hammond et al. do not disclose where the pre-alignment means comprises an elastically compressible member for flexibly engaging the sample. It is considered a design choice to have an elastically compressible member for flexibly engaging the sample to keep the sample from chipping or breaking.

Regarding claim 10, Hammond et al. disclose where the pre-alignment means comprise a spring-loaded arm for embracing the sample (Figure 2).

Regarding claim 11, Hammond et al. disclose where spring-loaded arm and a part of the feeding means are provided with an indentation for receiving the sample (Figure 1).

Regarding claim 17, Hammond et al. disclose where the sample is a solid dosage form (Figure 2).

Regarding claim 12, neither Hammond et al. nor Trygstad disclose where the means for feeding samples sequentially through the analyzing position is a rotating feeder wheel comprising at least one pre-alignment means for receiving at least one sample. However, Schilling discloses a means for feeding samples sequentially through the analyzing position is a rotating feeder wheel comprising at least one pre-alignment means for receiving at least one sample (Figure 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Hammond et al. to include a means for feeding samples sequentially through the analyzing position is a rotating feeder wheel comprising at least one pre-alignment means for receiving at least one sample as taught by Schilling since it would make it easier to analyze more samples in a shorter period of time.

Regarding claim 13, neither Hammond et al. nor Trygstad disclose where the rotating feeder wheel is connected to a sample receiver, which provides the feeder with samples to be analyzed. However, Schilling discloses where the rotating feeder wheel is connected to a sample receiver, which provides the feeder with samples to be analyzed (Figure 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Hammond et al. to include where the rotating feeder wheel is connected to a sample receiver which provides the feeder with samples to be analyzed as taught by Schilling since it would provide an even distribution of tablets.

Regarding claim 14, Hammond et al. do not disclose where the sample receiver is an on-line sample receiver and provides the pre-alignment means with samples. However, Schilling discloses where the sample receiver is an on-line sample receiver and provides the pre-alignment means with samples (Figure 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Hammond et al. to include where the sample receiver is an on-line sample receiver and which provides the pre-alignment means with samples as taught by Schilling since this would help to give an accurate measurement for the sample.

Regarding claim 15, Hammond et al. do not disclose where the sample receiver is an at-line sample receiver, which provides the pre-alignment means with samples. However, Schilling discloses where the sample receiver is an at-line sample receiver, which provides the pre-alignment means with samples. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Hammond et al. to include where the sample receiver is an at-line sample receiver, which provides the pre-alignment means with samples as taught by Schilling since this would aid in having the measurement of the samples more accurate.

Regarding claim 16, Hammond et al. do not disclose where the at-line sample receiver comprise a conical rotating part defining the bottom of an open vessel with cylindrical geometry, where samples fall upon the conical rotating part to be sequentially aligned before entering the pre-alignment means in the

feeder wheel. However, Schilling discloses where the at-line sample receiver comprise a conical rotating part defining the bottom of an open vessel with cylindrical geometry, where samples fall upon the conical rotating part to be sequentially aligned before entering the pre-alignment means in the feeder wheel (Figure 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Hammond et al. to include where the at-line sample receiver comprise a conical rotating part defining the bottom of an open vessel with cylindrical geometry, where samples fall upon the conical rotating part to be sequentially aligned before entering the pre-alignment means in the feeder wheel as taught by Schilling since this would make it easier to sort the tablets.

Regarding claim 25, Hammond et al. do not disclose where the sample receiver is a transport line connected on-line to an instrument which performs a tabletting process. However, Schilling discloses where the sample receiver is a transport line connected on-line to an instrument which performs a tabletting process (Figure 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Hammond et al. to include where the sample receiver is a transport line connected on-line to an instrument which performs a tabletting process as taught by Schilling since this would ease in the measuring of the sample.

Regarding claim 26, Hammond et al. disclose where the dosage is a tablet (Figure 2).

5. Claims 18-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hammond et al. in view of Schilling and Trygstad.

Regarding claim 18, Hammond et al. disclose a means for temporarily fixing the sample at the analyzing position. Hammond et al. do not disclose feeding a sample sequentially through the sample presentation apparatus. However, Schilling discloses where feeding a sample sequentially through the sample presentation apparatus (Figure 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Hammond et al. to include where feeding a sample sequentially through the sample presentation apparatus as taught by Schilling since this would make it easier for the samples to be placed in the analyzing position. Hammond et al. does not disclose an open position to allow the sample to be transported to an ejection position. However, the invention of Hammond et al. has to have the holding parts open in order to eject the sample to place another one in place. What is not disclosed by Hammond et al. is where the first and second holding parts defines apertures within the parts and where the first and second apertures together define an effective aperture in the closed position. However, Trygstad discloses where the first and second holding parts define apertures within the parts (Figures 1 and 2; 30,36). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Hammond et al. to include where the first and second holding parts defines apertures within

the parts as taught by Trygstad. By adding this feature the artisan would be able to analyze tablets of various sizes.

Regarding claim 19, Hammond et al. disclose where the measurement is performed by irradiating the sample with at least one measuring beam while the sample is temporarily fixed (Figure 2).

Regarding claim 20, Hammond et al. disclose where the measurement is an optical measurement (Abstract).

Regarding claim 21, Hammond et al. disclose where the optical measurement is carried out by means of near-infrared spectrometry (Abstract).

Regarding claim 22, Hammond et al. disclose where the optical measurement is carried out by means of near-infrared spectrometry (Abstract).

Regarding claim 23, it is considered a design choice and well within the purview of the skilled artisan to have the radiation beam a microwave beam since this would give the artisan a beam with a shorter wavelength and a more precise measurement.

Response to Arguments

6. Applicant's arguments filed 03/11/04 have been fully considered but they are not persuasive. In response to Applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into

account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Applicant has argued "Schilling fails to suggest an automated means for feeding a sample through the analyzing position". However, Applicant admits that Schilling does provide an automated means on page 2, line 29 of the instant application.

Applicant has argued that since the Hammond reference teaches a manual operation that it cannot be made obvious to the instant application. However, the replacement of a manual operation with an automatic operation is a design consideration within the skill of the art. In re Venner, 262 F.2d 91, 120 USPQ 192 (CCPA 1955).

In response to Applicant's argument that the combination of the references would destroy the intended structure and "there is no logical purpose to automatically and then dispense a sample into a sample compartment, and then subsequently manipulate the sample manually to secure it in the sample compartment", the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to André K. Jackson whose telephone number is (571) 272-2196. The examiner can normally be reached on Mon.-Thurs. 7AM-4PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron Williams can be reached on (571) 272-2208. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.J.

May 10, 2004

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